

Therapeutic Goods (Charges) Amendment Regulations 2000 (No. 2) 2000 No. 125

EXPLANATORY STATEMENT

STATUTORY RULES 2000 No. 125

Issued by authority of the Parliamentary Secretary to the
Minister for Health and Aged Care

Therapeutic Goods (Charges) Act 1989

Therapeutic Goods (Charges) Amendment Regulations 2000 (No.2)

Section 3 of the *Therapeutic Goods (Charges) Act 1989* (the Act) states that the *Therapeutic Goods Act 1989* is incorporated, and is to be read as one, with the Act.

Subsection 4(1) of the Act provides that annual charges are payable for maintaining registration and listings of therapeutic goods in the Register. Subsection 4(1A) of the Act provides that where more than one therapeutic good is "grouped" and each of the "grouped" therapeutic goods is covered by the same registration or listing number, then a single annual charge will apply for maintaining all the registered or listed therapeutic goods covered under the same grouping.

Section 5 of the Act enables the Governor-General to prescribe the level of charges that are payable for maintaining goods in the Register or for maintaining grouped therapeutic goods in the Register.

The purpose of the amending regulations is to increase the annual charges that are payable in relation to therapeutic devices, in order to meet the government's requirement that the Therapeutic Goods Administration (TGA) operate on a full cost-recovery basis. The Medical Industry Association of Australia (MIAA), which is the peak industry body in relation to therapeutic devices, considered the amendments being made to adjust the fees and charges payable under both the Therapeutic Goods Regulations and the Therapeutic Goods (Charges) Regulations provide equity across the listed and registered devices market and will give incentives for new products.

It was agreed with MIAA that greater emphasis would be placed on annual charges as a revenue base for achieving cost recovery.

The Amending Regulations provide for:

- * annual charges for listed devices to increase from \$300 to \$450 per annum,
- * annual charges for registered devices to increase from \$490 to 5900 per annum.

Details of the amending Regulations are set out in the Attachment.

The Regulations commence on 1 July 2000.

ATTACHMENT

Therapeutic Goods (Charges) Amendment Regulations 2000

Regulation 1 states that the title of these regulations will be the Therapeutic Goods (Charges) Amendment Regulations 2000 (No

Regulation 2 provides that these regulations commence 1 July 2000.

Regulation 3 provides that these regulations amend the *Therapeutic Goods (Charges) Regulations 1990* as provided in Schedule 1.

SCHEDULE 1 - AMENDMENTS

Item 1 increases the annual charges for maintaining registrations of therapeutic devices from \$490 to \$900.

Item 2 increases the annual charges for maintaining listable therapeutic devices from \$300 to \$450.

Item 3 increases the annual charges for maintaining registrations of registered therapeutic devices that have been grouped, pursuant to section 16 of the *Therapeutic Goods Act 1989*, from \$490 to \$900. The effect of "grouping" is to enable the sponsor of each of the goods covered by a "grouping" to use the same registration number for all grouped goods, and to pay only one annual charge for all goods grouped. But for "grouping" pursuant to section 16 of the *Therapeutic Goods Act 1989*, the sponsor would be required to use different registration numbers for each product being supplied, and to pay a separate annual charge for each product included in the Register.

Item 4 increases the annual charges for maintaining listings of grouped listable therapeutic devices, from \$300 to \$450.